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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,604	MCLACHLAN ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to an isolated antibody or antigen binging fragment for IGSF9 or LIV-1, classified in class 530, subclass 387.1.

II. Claims 9-18 and 32-33, drawn to a kit and method of treating a mammal exhibiting a neoplastic disorder comprising administering a therapeutically effective amount of an antibody to IGSF9 or LIV-1or antibody combining with at least one chemotherapeutic agent, classified in class 424, subclass 130.1.

III. Claims 19-23, 43 and 34 in part drawn to a vaccine for treating cancer comprising to IGSF9 or LIV-1 polypeptide or a fragment and physiologically acceptable carrier, classified in class 530, subclass 300 and 350.

IV. Claims 34 in part drawn to a vaccine for treating cancer comprising to IGSF9 or LIV-1 nucleic acid or a fragment and physiologically acceptable carrier, classified in class 536 subclass 23.1.

V. Claims 24, drawn to a method of inducing an immune response in a patient in need of treatment or prevention of cancer comprising administering a polypeptide vaccine comprising IGSF9 or LIV-1, classified in class 514, subclass 2.

VI. Claims 31, drawn to a vaccine for treating cancer comprising an anti-idiotypic antibody that immunologically mimic the IGSF9 or LIV-1antigen, classified in class 530, subclass 387.1.

VII. Claims 25 an 29-30 in part and 26-27 drawn to a method of diagnosing cancer by detecting overexpression of IGSF or LIV-1, wherein the overexpression is detected by nucleic acid amplification or hybridization, classified in class 435, subclass4, and 6.

VIII. Claims 25 and 29-30 in part and 28, drawn to a method of diagnosing cancer by detecting overexpression of IGSF or LIV-1,wherein the overexpression is detected by an

antibody to IGSF9 or LIV-1 or an antigen binding fragment, classified in class 435 subclass 4, 7.1adn 7.23.

IX. Claims 35-36, drawn to an antisense nuclei acid up 50 nucleotide in length which inhibits the expression of IGSF9 or LIV-1, classified in class 536, subclass 24.1.

X. Claims 37, drawn to a method for inhibiting the expression of IGSF9 or LIV-1 in cells or tissues comprising contacting cells or tissues with the nucleic acid classified in class 435, subclass 24.1.

XI. Claims 38-40, drawn to an isolated nucleic acid, a vector and host cell, classified in class 536, subclass 23.1 and class 435, subclass 320.1.

XII. Claims 41-42, drawn to an isolated polypeptide and a composition, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons.

The polypeptide of Group III and the antibody of Group II are patentably distinct for the following reasons:

1. While the inventions of both Group II and Group III are polypeptides, in this instance the polypeptide of Group III is a single chain molecule, whereas the polypeptide of Group II encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions. Thus the polypeptide of Group III and the antibody of Group II are structurally distinct molecules; any relationship between a polypeptide of Group III and an antibody of Group II is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group II. Furthermore,

antibodies which bind to an epitope of a polypeptide of Group III may be known even if a polypeptide of Group III is novel. In addition, the technical literature search for the polypeptide of Group III and the antibody of Group II are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

2. The polypeptide of group III and polynucleotide of group IV are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group IV does not necessarily encode a polypeptide of group III. Similarly, the nucleic acid molecule is complementary to the coding sequence, and therefore would not encode the polypeptide of group III. Furthermore, the information provided by the polynucleotide of group IV can be used to make a materially different polypeptide than that of group III. In addition, while a polypeptide of group III can made by methods using some, but not all, of the polynucleotides that fall within the scope of group IV, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups IV and III are patentably distinct.

3. The polynucleotide of group IV and the antibody of group II are patentably distinct for the following reasons. The antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group IV will not encode an antibody of group II, and the antibody of group II cannot be encoded by a polynucleotide of group IV. Therefore the antibody and polynucleotide are patentably distinct.

4. Inventions Group I/II, I/ VIII, III/V, IV/X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). For example, in the instant case the antibody of Group I can be used to detecting or treating the patient in vivo alone, as opposed to **(or its use in)** being used in treating patient with neoplastic disorder with other chemotherapeutic agent of group II or VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other Groups because each group requires a different non-patent literature search due to each group comprising different methods and steps, restriction for examination purposes as indicated is proper.

5. Groups II, V, VII, VIII or X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II, V, VII, or X are unrelated because each invention required different treatment effect and have different modes of operation. Therefore, each invention may need different patient population or biological samples from different patients. Invention II, III, or X are methods for treating cancer patient or precancer patients with different materials, antibody (II) or polypeptide (III) or DNA as vaccine (X). Inventions VII or VIII are method for in vitro detecting expression of IGSF or LIV-1 using antibody (VIII) or using a polypeptide (VII).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to

each group comprising different products and/or method steps, Therefore, restriction for examination purposes as indicated is proper.

Inventions I, III, IV, XI, XII are patentably distinct products.

Furthermore, if applicants elect any one of the groups set forth above, further **restriction** is required under 35 U.S.C. 121:

A. Polypeptide: SEQ ID NO: 2, 4, 6, , 8, 22-27, or 29.
B. Polynucleotide: SEQ ID NO: 3, 5, 12-20, or 21

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must first elect one from Groups I-XII, and then elect one corresponding sequence either from polypeptide list of A, or polynucleotide list of B even though the requirement is traversed. Applicant is advised that neither I - XII nor any SEQ ID NO from list A or list B is species election requirements; rather, each of I – XII and single SEQ ID NO from list A or list B is a restriction requirement. For example, if applicants elect group I, applicants is required to further elect one single peptide from sequence list A, if applicant elect group XI, applicant is required to further elect one singe nucleotides from sequence list B.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named

inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
PATENT EXAMINER
10/11/08